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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/017,715	02/03/98	JI	H 188.0810003

EXAMINER

HM12/0922
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WASHINGTON DC 20005-3934

ART UNIT	PAPER NUMBER
JOHNSON, N	12

DATE MAILED: 1642
09/22/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/7/99 & 07/23/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days,~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 10-12, 14-79 is/are pending in the application.
Of the above, claim(s) 10-12, 14-15, 79 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 16-78 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 16 7/13/98
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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1. Applicant's election with traverse of Group I, claims 16-79 in Paper No. 11, filed 7/23/99 is acknowledged. The traversal is on the ground(s) that no serious search burden is involved in examining both the claims of Group I, drawn to polynucleotides, and Group II, drawn to polypeptides. The applicant argues that "no arguments have been made explaining why it would impose an undue burden to examine the polynucleotide and polypeptide claims together." This is not found persuasive. As explained in the restriction requirement, the claims of Group I are classified in class 536, subclass 23.5 while the claims of Group II are classified in class 530, subclass 350. Thus, the examination of both groups would require different searches in the U.S. Patent Shoes and the consideration of different patentability issues. Because these inventions are distinct for these reasons, given in the previous restriction requirement, and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made FINAL.

2. Newly submitted claim 79 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Elected Group I is directed at the polynucleotide product of SEQ ID NO:1. Newly added claim 79 is drawn to a material different polynucleotide product, SEQ ID NO:12. Since applicant has received a restriction requirement and elected Group I, claim 79 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 1-9 and 13 have been canceled.

Claims 16-79 have been added.

Claims 10-12 and 14-15 and 79, drawn to non-elected inventions, are withdrawn from examination.

Claims 16-78 are examined on the merits.

4. Claims 17, 19, 22-23, 26, 28-29, 34-35, 38, 40-41, 48-49, 52, 54-55, 62-63, 66, 68-69, 72-75 and 77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Literal support is not found in the specification for the following recitations, and they are considered to be new matter:

"nucleotides 15 to 392 of SEQ ID NO:1" (claim 17)

"nucleotides 12 to 392 of SEQ ID NO:2" (claim 19)

"a heterologous polynucleotide" (claims 22, 34, 48, 62)

"said heterologous polynucleotide encodes a heterologous polypeptide" (claims 23, 35, 49, 63)

"operably associated with a heterologous regulatory sequence" (claims 26, 28, 38, 40, 52, 54, 66, 68)

"except for one to thirty conservative amino acid substitutions" (claim 72)

"wherein said substitutions is not more than 10" (claim 73)

"wherein said substitutions is not more than 5" (claim 74)

"wherein said substitutions is not more than 3" (claim 75)

"nucleotides 15 to 392 of SEQ ID NO:1" and "nucleotides 18-392 of SEQ ID NO:1" (claim 77).

5. Claims 31-42, 71-76 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials.

The specification lacks complete deposit information for the deposit of the plasmid clone 97856. It is not clear that clones possessing the identical properties of 97856 are known and publicly available or can be reproducibly isolated from nature without undue experimentation. Exact replication of a cDNA clone is an unpredictable event. It is unclear that one of skill in the

art could derive cDNA clones identical to those claimed. Undue experimentation would be required to screen all of the possible cDNA clones species to obtain the claimed clone.

Because one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the claimed clone, a suitable deposit for patent purposes, evidence of public availability of the claimed clone or evidence of the reproducibility without undue experimentation of the claimed clone, is required.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

© the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years

after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If deposits are made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the clone described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

6. Claims 16-78 are free of the art

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nancy A Johnson
Primary Examiner

September 17, 1999